FDA 510(k) Premarket Notification

K922461 COMFEEL WOUND DRESSING ORD

CLEARED

Aug 17, 1992
83 days to decision

K922461 · Product code: **KMF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k922461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bandage, Liquid (KMF)
Date received	May 26, 1992
Decision date	Aug 17, 1992
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	RICHARD A HAMER
Website	http://www.coloplast.com/
510(k) history	71 submissions · 68 cleared · 1983-2023

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...